STATEMENT OF ROBERT P. CHARROW, ESQ.

BEFORE

THE HOUSE BUDGET COMMITTEE
HEALTH TASK FORCE

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MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

I am deeply honored at being asked to share some of my experiences, perspectives, and thoughts with the Committee. Health care– the way it is provided, the way it is regulated, and the way it is funded– is of critical importance to most Americans. As our population ages, concerns about the quality, availability, and affordability of health care will only grow. These concerns with attendant political and societal pressures will focus primarily on Medicare– a system designed in 1965 and largely modeled after the way medicine was practiced in that era.[1] The practice of medicine, though, has changed dramatically– both organizationally and scientifically– and is remarkably different now than it was then. Medicare, though, has remained fundamentally unaltered. The dissonance between the way medicine is practiced and the way Medicare operates has given rise to regulatory burdens and inefficiencies that frustrate all– hospital administrators, family physicians, and Medicare beneficiaries alike.

I would like to share with the Committee my concerns in a few specific areas by asking and answering three basic questions. First, has the Medicare system simply become too complex and too mired in arcane rules that can only be understood by lawyers and accountants? Second, are the rules that govern the system truly cost justified and has anyone bothered to test them? Third, do the rules and red tape unnecessarily diminish the amount of funds available for medical care?

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[1] The Medicare and Medicaid programs were enacted in 1965 as Titles XVIII and XIX of the Social Security Act, respectively, and began

1. **Is the Medicare Program Mired in Too Much Regulation?**

With the permission of the Chair, I would like to relate a personal story that highlighted for me the complexity and opaqueness of Medicare to providers and beneficiaries alike.

About a decade ago, when my father was dying of prostate cancer, the family, including my father, had to make some tough decisions concerning what type of care he was to receive under Medicare. The choice was between home health and hospice care. My mother gathered the details from a home health agency and a hospice in Los Angeles, where my parents lived. When she told me the level of care and the various restrictions each claimed that federal law required, I knew that something was amiss. I am a health care lawyer and for once, I thought I would be able use my esoteric specialty to benefit my family. This turned out to be only partially true. I needed help.

I quickly confirmed that what the providers had told my mother was wrong. The coverage that the home health agency offered to my father appeared to be inconsistent with existing law. A quick check of the federal rules and other program documents confirmed my initial suspicion. Learning what my father would be entitled to receive if he opted for hospice care proved to be more challenging. The statutory law governing hospice care had been significantly changed and the information given to my mother had been based on the old laws. This was not surprising, since the regulations implementing those changes had never been issued by the Health Care Financing Administration.

As a Washington health care lawyer, I was used to dealing with the people at HCFA. After making a few phone calls, I learned who at HCFA

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operation on July 1, 1966. *See* Title I, Social Security Act Amendments

was setting policy for hospice care. I called him, spent about 45 minutes on the phone with him, and came away with lots of information about how HCFA would be implementing the statutory changes. I called both the home health agency and the hospice in Los Angeles, told them who I was, and provided them with about two hours worth of free legal advice. My father ultimately opted for hospice care. Had I not suspected that what we had originally been told was wrong, had I not known how to use the Code of Federal Regulations and various HCFA manuals, and had I not known whom to contact at HCFA, we would have made the wrong treatment decision and my father would have been provided with fewer benefits than he was legally entitled to receive.

That was my first experience as a quasi-consumer of federal health care services, and it was both sobering and frightening. It drove home, as nothing else could, the basic fact that our health care system is simply too complex and inelegant. If I, as a health care lawyer, could not easily find the law, how can we expect consumers or even providers to understand the law?

The Medicare statute is more than 400 pages long and is not a model of clarity. In theory, HCFA is supposed to issue regulations to give life to the statute. The regulatory process, though, takes years, and usually what you end up with is a rule that is comprehensible and accessible only to lawyers. Medicare's regulations take up about 1,300 pages in the Code of Federal Regulations. But that's only the beginning. On top of the statute and regulations– all of which are accessible to the public, but essentially unreadable– are Medicare issuances, publications, program memoranda, manuals, Inspector General Alerts, advisory opinions, local medical review policies, coverage decisions, Departmental Appeals Board rulings, and so on.

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of 1965, Pub. L. No. 89-97, 79 Stat. 286.

All told, the 400-page statute has given birth to more than 100,000 pages of secondary Medicare laws, guidelines, issuances, and the like. All of these affect the level of services and how they are delivered. Yet, little of this information is readily available or easily understandable. The Medicare system is simply collapsing under its own regulatory weight.

2. Is the Current Level of Medicare Regulation Cost Justified?

There can be little doubt that Medicare is mired in regulation and that the regulation impedes both providers and beneficiaries. The second question, though, is more fundamental– is the current level of regulation necessary? Astonishingly, we do not know. Before the government buys a new $2 billion weapons system, it tests the system for years and requires the contractor to make necessary design and manufacturing changes. Before HCFA implements a regulatory initiative that could cost significantly more than $1 billion and will affect hundreds of thousands of providers and millions of beneficiaries, does it do any "testing?" The answer is usually "no." In short, we are making changes to a $200 billion system without first testing the impact of those changes.

To illustrate this, let's look at the rules that govern fraud, waste, and abuse. Everyone would agree that fraud is evil, is criminal, and should be punished decisively. Moreover, fraud is relatively easy to define. We not only know it when we see it, but we can articulate why some conduct is fraudulent and other conduct is not. For example, the hospital chain that billed Medicare for treating patients that were never hospitalized was committing fraud. Or the physician who bills Medicare for a long office visit, when in fact he saw the patient for less than three minutes is also committing fraud. The federal laws governing fraud apply equally across the board from defense contractors to universities to hospitals, physicians, clinical laboratories and even beneficiaries. Interestingly enough, although we have been led to

believe that healthcare is rife with fraud, in fact the numbers indicate to the contrary. The Inspector General, for instance, reports having recovered less than $500 million on account of all types of improper conduct; when compared to the about $400 billion spent on Medicare and Medicaid, the actual percentage of measurable fraud is relatively small– medicine is about 99 and 44 one hundredths percent pure; so far, so good.

Like fraud, most of us consider that kickbacks should also be outlawed. The physician who accepts a 20% kickback in exchange for ordering a specific battery of tests from a specific clinical lab should be treated no differently than the defense contractor that gets secret kickbacks from its subcontractors. Kickbacks in Medicare are bad– they promote overpayment and over-utilization and inappropriately interject financial considerations into medical decisionmaking. The antikickback law that governs federal healthcare programs, though, is far broader and procedurally distinct from the one that applies to the other sectors of the government. In fact, these laws are so expansive that they prohibit conduct that is perfectly legitimate in other settings.

Under the antikickback statute as written, for example, it is illegal for a physician to sell his practice if the sale includes "goodwill." No arrangement– whether it is a complex merger, acquisition, joint venture, or a simple purchase of hospital or medical office equipment-- can be seriously considered without evaluating its antikickback implications. Moreover, the healthcare antikickback laws vest extraordinary discretion in the Office of Inspector General to modify, to interpret and to apply these already broad laws. The law effectively has transferred significant healthcare policy decisionmaking from the Congress and the political appointees to career OIG attorneys with no formal training in medicine and little in developing or testing cogent policy.

How did all of this happen? Congress first enacted an antikickback law for Medicare in 1972;[2] that law, however, was somewhat ambiguous. To eliminate that ambiguity, Congress in 1977 amended the law and broadened its coverage.[3]

The new law went beyond prohibiting kickbacks and other forms of fraud, and sought to use the threat of prosecution as way of regulating "abuse" and "waste," terms that have no real legal meaning. Not unexpectedly, the new law proved to be too broad, effectively outlawing all sorts of legitimate business arrangements: a physician could not sell his practice, a physician couldn't sublease space in his office to another physician if that sublessee referred patients to the owner and so on. To cure this problem, Congress in 1987, enacted legislation that authorized the Secretary of Health and Human Services with the approval of the Attorney General to develop so-called safe harbors.[4] The theory was that if a person who conformed his or her arrangement to the conditions of the safe harbor, then that person would not be prosecuted even though the arrangement technically violated the antikickback law. In 1991, the Secretary issued the first ten safe harbors. Today there are fifteen safe harbors, the last two

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2 *See* section 242(b), Social Security Amendments of 1972, Pub. L. 92-602, 86 Stat. 1419-1420

3 *See* Medicare-Medicaid Antifraud and Abuse Amendments of 1977, Pub. L. No. 95-142, § 4(a), 91 Stat. 1175, 1179-1181 (1977). In lieu of the phrase "kickback or bribe," as used in the 1972 law, the amended version banned "any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind" to induce a referral. 42 U.S.C. § 1396h(b)(1)(1977). The antikickback law has been recodified as section 1128B(b), Social Security Act, 42 U.S.C. § 1320a-7b(b).

4 . *See* section 14, Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. 100-93.

having been issued in November 1999.[5] There are safe harbors for renting office space, for receiving a discount on the purchase of equipment, for obtaining a warranty and for a variety of other normally straightforward business arrangements.

The safe harbor system though had its problems. The Inspector General was reluctant to issue safe harbors and when she did they tended to be extraordinary rigid. Moreover, it took years to issue a new safe harbor. Thus, as part of the Health Insurance Portability and Accountability Act of 1995, Congress required the IG to issue advisory opinions– these advisory opinions are essentially single transaction, one time safe harbors. In deciding whether to approve a proposed transaction, the OIG must consider, among other things, whether the proposed arrangement will cause overutilization or adversely affect patient care. Should these types of policy decisions, requiring expertise in medical economics and medicine itself be made by lawyers in the Inspector General's Office? I think not. Those whose training is law enforcement tend to see "waste" and "abuse" everywhere. Indeed, the IG has expressly noted that the advisory opinion process "permits this Office to protect specific arrangements that contain limitations, requirements, or controls that give adequate assurance that Federal health care programs cannot be abused." Advisory Opinion 98-14 (quoting from 62 Fed. Reg. 7350, 7351 (Feb. 19,1997).

Moreover, is it wise to effectively require people to seek governmental approval before entering into a normal business arrangement? The perils associated with violating the antikickback law are so great that even those

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[5] See 42 CFR § 1001.952; *see* 56 Fed. Reg. 35,799 (July 29, 1991); 57 Fed. Reg. 52,723 (Nov. 5, 1992); 59 Fed. Reg. 37,202 (July 21, 1994); 61 Fed. Reg. 2,122, 2,125 (Jan. 25, 1996); 63 Fed. Reg. 46,676 (Sept. 2, 1998);

who are providing free goods or services to health charities have sought advisory opinions first. Clearly, this is good for lawyers, since we draft the advisory opinion requests. But is it good for medicine and health care and does it make sense?

The most interesting aspect of the antikickback saga is that a broad antikickback law may not make any sense today. Medicare payment has changed since 1977 so that overutilization is far less of a problem than it was then. For example, in 1977, hospitals were reimbursed for their costs– the more they spent, the greater their reimbursement. If they paid kickbacks to suppliers, those kickbacks were passed through to the government. In such a setting a broad antikickback law made commercial sense. In 1983, however, Congress changed the way in which hospitals were paid so that they were no longer reimbursed for their expenses, but instead were paid a fixed fee for treating a given illness. If they paid kickbacks, the hospital, not the government, would eat the cost. Correspondingly, the introduction and quick spread of fee schedules and capitated payment arrangements in the late 1980s and early 1990s also shifted the cost of kickback from the government to private party. In short, there is now a serious question as to whether this complex antikickback mechanism is even cost justified. Surprisingly, though, no one at HHS has indicated any interest in studying the problem or attempting to resolve it. The antikickback laws provide the government with a way to micromanage medical care and there does not seem to be any desire to give up that authority.

3. Can Over Regulation Affect the Quality of Care?

The antikickback law is symptomatic of a system that is overly complex and overly regulated. Neither complexity nor regulation is free– the more regulation, the less that can be spent on health care. The real question

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64 Fed. Reg. 63,503 (Nov. 19, 1999); and 64 Fed. Reg. 63,517 (Nov. 19,

is how much regulation is optimum, and for that we must be willing to conduct experiments or develop models to see how best to curtail regulation. There is certainly evidence, albeit anecdotal, to suggest that over-regulation adversely affects the quality of care by shifting resources from the medical treatment to paper pushing and compliance activities.

You might ask, how can this be? After all, HCFA constantly reminds us that Medicare's transaction costs are 80% less than those of private insurers. HCFA has achieved low government transaction costs by shifting those costs from the government to the private sector. For example, private insurers take on the responsibility for conducting compliance programs and auditing functions. Not so with Medicare; HHS expects providers to undertake those functions.

Many now believe that when you add in all the compliance activities and added administrative burdens associated with Medicare, its overall transaction costs far exceed those of the private insurers.

Given that providers– whether hospitals or physicians– are paid fixed fees, those extra transaction costs must come from somewhere and, in many cases, they are coming out of the treatment side of the office, rather than the administrative side. Given a choice, do we want our hospitals to hire more coding clerks and compliance officers, or more nurses and physicians?

Conclusion

I am not advocating that we abandon regulation nor am I suggesting that regulation is unnecessary. Rather, I am advocating for the notion that regulation is not free. We should at least determine empirically which regulations make sense, and should be retained and which are counter-productive and ought to be abandoned.

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